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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/051,719 | 01/16/2002 | Matthew T. Scholz | 57338US002 | 8633 |

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EXAMINER

CHOI, FRANK I

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1616

DATE MAILED: 12/03/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/051,719

Applicant(s)

SCHOLZ ET AL.

Examiner

Frank I Choi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 22-24,31,32,35,36,40 and 44-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21,25-30,33,34,37-39 and 41-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-53 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 247.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 40, 44-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 5. In response, to an Office Letter (7/24/2003) indicating that Applicant had not complied with the election of species requirement, Applicant elected as the species iodophor, lactic acid, an acrylate polymer and amphoteric surfactant. Applicant indicates that elected species are all encompassed by the claims of group I. However, the species "acrylate polymer" does not indicate that it includes side-chain functional amine groups, or that the polymer contains at least 15wt% of an amine group-containing monomer. As such, claims 22-24 do not appear to read on the elected species. Applicant has not indicated what claims read on amphoteric species, however, it is assumed that claims 31, 32, 35, 36 do not read on the claimed invention. Applicant elected said species with traverse in Paper No. 8. Examiner has duly considered Applicant's arguments but deems them unpersuasive. Applicant argues that the generic claim includes sufficiently few related species that search and examination of all the species at one time would not impose a serious burden on the Examiner. Examiner notes that other than lactic acid, Applicant has not elected species but actually subgenres. It is uncertain whether Applicant is arguing by using "sufficiently few related species" by using subgenres that that species that make the subgenres are not patentably distinguishable from each other, i.e. that they are obvious variants of each other. In which case, Applicant is required to submit evidence of the same or explicitly indicate the same. Examiner assumes that this is not the case. In which case, Applicant has provided no evidence that the

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generic claim includes sufficiently few related species that search and examiner of all the species at one time would not impose a serious burden. The prior art (see below) and Applicant's own Specification (Pgs. 11, 13, 14, 17-27), shows that iodophors can be formulated with a number of polymer carriers, that there is an extensive number of types of hydroxycarboxylic acid buffers, that there are numerous species of polymers and monomers which can be used to form the polymers and numerous species of surfactants. As such, the possible number of combinations of iodophor, hydroxycarboxylic acid buffer, and polymer, and, optionally, surfactant are so numerous as to constitute a burden on Examiner. As such, claims 22-24, 31, 32,35,36, 40, 44-53 will be withdrawn as directed to a nonelected invention with claims 1-21, 25-30, 33, 34, 37-39, 41-43 will be prosecuted as being drawn to the elected invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections

of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. Please update references to related Application to indicate the Application Serial Number.

Claim Rejections - 35 USC § 101/112

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-9, 28, 37, 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A single claim which claims both a product and process steps of using the product is indefinite under 35 U.S.C. 112, second paragraph. See MPEP Section 2173.05(p)(II). Herein, the claims 7-9, 28, 37, 42 claim an antiseptic composition and the process steps of using said composition, i.e. for reducing normal skin flora, applying to rabbit eyes and/or applying to tape or human skin.

Such claims are also rejected under 35 U.S.C. 101 based on the theory that the claim is directed to neither a "process" nor a "composition of matter," but rather embraces or overlaps

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two different statutory classes of invention set forth in 35 U.S.C. 101 which is drafted so as to set forth the statutory classes of invention in the alternative only. Id.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-21, 25-30, 33, 34, 37-39, 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kross et al. (US Pat. 5,618,841) in view of Brink et al. (US Pat. 5,173,291) and Beach (US Pat. 3,380,923).

Kross teaches the antimicrobial compositions containing iodophores, lactic acid, surfactants and the formation of films incorporating the above to form protective barriers having viscosities generally in the range from about 200 to 3,000 centipoise, using a suitable polymeric material which are known to those skilled in the art (See entire document, especially Columns 3-5, Column 6, lines 1-6, Examples I, II, II, IV, V).

Brink et al. teach that organic solvents such as ethyl alcohol or isopropyl alcohol are often used as solvent carrier, however, they can be irritating to skin tissue and are not suitable for use on sensitive tissue such as burn wound sites and mucosal tissue and that the vapors are often toxic and/or flammable (Column 1, lines 48-55). It is taught that increasing the water and bodily fluid resistance of topically applied antimicrobial agents increase the substantivity and length of activity and that compositions that can form a water insoluble film can, in addition to providing a long lasting antimicrobial activity, also provide a protective layer for sensitive tissue (Column 1,

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lines 36-48). An composition is taught which is water-based, nonflammable, nonirritating and form low tack or tack free films, comprising iodine as the antimicrobial agent, and a mixture of monomers, including acrylates, in which the relative water resistance of the ultimate film is determined by the selection of comonomers to be used with iodine complexing comonomer and by adjusting the ratio of water insoluble comonomers to water soluble comonomers (Column 4, lines 5-68, Column 5, lines 35-68, Columns 6,7). It is taught that the emulsifiers commonly used include amphoteric surfactants and that the pH of the emulsions may be adjusted by the appropriate acidic species (Column 8, lines 28-63). It is taught that the films may be removed by covering with a surgical drape which includes a pressure-sensitive adhesive layer and by removing the surgical drape the film that is contacted by the adhesive layer is also removed (Column 9, lines 55-61).

Beach teaches that amphoteric surfactants, containing amine and sulfate groups, are suitable for use in preparing iodophore germicides suitable for use in the dairy industry (Columns 1, 2).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination of iodophor, lactic acid, an acrylate film-forming polymer, amphoteric surfactant and water. However, the prior art amply suggests the same as it is known in the art to prepare film-forming compositions containing iodophore, lactic acid, film-forming polymers, including acrylate polymers, and surfactants, including amphoteric surfactants. Further, one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the combination would form an antimicrobial film suitable for use in the dairy field as a teat dip.

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Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-21, 25-30, 33, 34, 37-39, 41-43 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 16-25, 27, 29-44, 47, 48-60 of copending Application No. 10/052,158 in view of Kross et al. (US Pat. 5,618,841), Brink et al. (US Pat. 5,173,291) and Beach (US Pat. 3,380,923).

The cited claims of the above-mentioned application teach a film forming composition comprising polymer containing a hydrophobic polymer, such as methacrylic, water, a surfactant, such as an amphoteric surfactant, which can contain an antimicrobial agent, such as iodophor, and a hydroxy-carboxylic acid buffer, such as lactic acid.

Kross et al. (US Pat. 5,618,841), Brink et al. (US Pat. 5,173,291) and Beach (US Pat. 3,380,923) are cited herein for the same reasons as above and are incorporated herein to avoid repetition.

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The difference between the claims of the cited application and the claimed invention is that the prior art does not expressly disclose the combination of iodophor, lactic acid, an acrylate film-forming polymer, amphoteric surfactant and water. However, the prior art amply suggests the same as it is known in the art to prepare film-forming compositions containing iodophore, lactic acid, film-forming polymers, including acrylate polymers, and surfactants, including amphoteric surfactants. Further, one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the combination would form an antimicrobial film suitable for use in the dairy field as a teat dip.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

This is a provisional obviousness-type double patenting rejection.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached on (703) 308-2927. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

November 29, 2003



JOHN PAK
PRIMARY EXAMINER
GROUP 1600